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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,348	11/14/2003	Janakiraman Ramachandran	021958-001510US	2395

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,348	RAMACHANDRAN ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 11-9-2007 is acknowledged. Claims 9 and 13 have been amended.

Claims 1-20 are pending. Claims 1-8 and 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 9-15 are currently under examination.

Claim Rejections Withdrawn

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "incapacitated whole cell bacterial vaccine" is withdrawn in light of Applicant's arguments.

The rejection of claims 9 and 13 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term the singular term "bacterium" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 9-10, 13-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4 and 8-9 of U.S. Patent No. 6,913,753 id maintained for reasons of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to methods of inducing a protective immune response against bacterial pathogen utilizing an incapacitated whole cell bacterial vaccine comprising the pathogenic bacteria that has been incapacitated by the expression of a recombinant promoter operably linked to a polynucleotide encoding a gene product. Specifically the bacterial vaccines incapacitated by a Lys negative bacteriophage anticipate the instant claims.

Applicant has indicated that a Terminal Disclaimer will be filed in response to this rejection. As no Terminal Disclaimer has been received by the Office, the rejection is maintained.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 9-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Majarian et al. (U.S. Patent 6,130,082 – IDS filed 3-21-2005) is maintained for reasons of record.

Applicant argues:

1. The attenuated invasive bacteria of Marjarian et al. are live and capable of replication

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the specification discloses that incapacitation is achieved by the simple expression of T7 polymerase (see page 16). Given that Majarian et al. disclose the use of the T7 promoter system (which includes the T7 polymerase) cells containing said promoter system would necessarily be "incapacitated".

As outlined previously, Majarian et al. disclose the use of vaccines comprising bacteria that recombinantly express flagellin fusion proteins (see abstract). Majarian et al. further disclose the use of the T7 promoter system (which includes the T7 polymerase)[see column 15, lines 10-26]. Since the use of the T7 promoter system results in the "hyper expression" of any recombinant protein in a bacterial system leads to them being incapacitated (see page 16 of the specification). Consequently, Majarian et al. anticipates all the limitations of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majarian et al. (U.S. Patent 6,130,082 – IDS filed on 3-21-2005), Kordyum et al. (U.S. Patent 6,773,899) and Wright et al. (Science, 1990, Vol. 249 pages 1431-1433 – IDS filed on 1-24-2005) is maintained for reasons of record.

Applicant argues:

1. A *prima facie* case of obviousness requires an Examiner to provide an explicit reason why the skilled worker would combine the known elements.

2. Majarian et al. neither shows nor suggest the use of incapacitated bacteria.

3. The cells of Majarian et al. were "previously attenuated" as opposed to the cells of the instant invention.

4. The cited art does not predict that incapacitation may be achieved simply by the hyper-expression of otherwise benign genes.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, contrary to Applicant's assertion, the rejection set forth not only a reason for combining the cited references but also why the skilled artisan would have a reasonable expectation of success (reiterated below).

With regard to Point 2, the specification discloses that incapacitation is achieved by the simple expression of T7 polymerase (see page 16). Given that Marjarian et al. disclose the use of the T7 promoter system (which includes the T7 polymerase) cells containing said promoter system would necessarily be "incapacitated".

In response to applicant's argument that the references fail to show certain features of applicant's invention (Point 3), it is noted that the features upon which applicant relies (i.e., that the bacteria not be previously attenuated) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to Point 4, the combination of the cited references would necessarily result in bacteria with the claimed characteristics. One would not need to "predict" that the over-expression of a gene would result in bacterial "incapacitation". Applicant is reminded that I the fact that he has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

As outlined previously, Majarian et al. disclose the use of vaccines comprising bacteria that recombinantly express flagellin fusion proteins (see abstract). Majarian et al. further disclose the use of the T7 promoter system (which includes the T7 polymerase)[see column 15, lines 10-

26]. Since the use of the T7 promoter system results in the "hyper expression" of any recombinant protein in a bacterial system leads to them being incapacitated (see page 16 of the specification).

Majarian et al. differ from the instant invention in that they don't disclose the recombinant expression of a protein that binds LPS generally or LPS binding protein specifically.

Kordyum et al. disclose the use of the T7 promoter system to overexpress biologically active proteins (see abstract).

Wright et al. disclose that LPS binding protein functions as an opsonin as it binds to the surface of bacteria and mediates their adhesion to macrophages.

Consequently, it would have been obvious for one of ordinary skill in the art to express the LPS binding protein disclosed by Wright et al. using the T7 promoter system in the recombinant vaccines of Majarian et al. in order to take advantage of the increased immunogenicity of the resulting vaccine (due to the opsonin function of the LPS binding protein). One would have had a reasonable expectation of success as Majarian et al. disclose the use of the T7 promoter system and Kordyum et al. disclose that genes encoding "any gene of interest" can be used with the T7 promoter system (see column 10, lines 1-2).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
October 14, 2008